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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,885	12/22/2003	Jason Otto	10557/294282	2164

30559 7590 03/27/2007
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EXAMINER

SWEET, THOMAS

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/743,885

Applicant(s)

OTTO ET AL.

Examiner

Thomas J. Sweet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-126 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-123, 125 and 126 is/are rejected.
- 7) ☒ Claim(s) 124 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: ____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :7/2/2004, 10/12/2004, 4/22/2005, 2/6/2006, 8/9/2005, 6/1/2006, 6/14/2006 and 1/18/2007.

DETAILED ACTION

Information Disclosure Statement

Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b).** Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The disclosure is objected to because of the following informalities: on page 5 line 15, the word "strike" is misspelled.

Appropriate correction is required.

Claim Objections

Claims 15, 82, 83, 105 and 118 are objected to because of the following informalities: each of these claims includes misspellings or typos. Appropriate correction is required. Please, review the claims of other misspellings or typos.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 12-18, 20-29, 31-37, 71-78, 80-86, 88-100, 102-108, 110-113, 115-123 and 125-126 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hood et al (US 5370699). Hood et al disclosed a knee prosthesis (fig. 1) comprising:

a femoral component adapted to fit on a distal end of a femur (30), the femoral component including a lateral condylar structure (at 35) and a medial condylar structure (at 33); and an accommodation structure configured to cooperate with the femoral component (44), the accommodation structure including a distal surface (underneath) and a posteriolateral proximal surface (92 such as see in fig. 11) that slopes toward the distal surface as the posteriolateral surface progresses in a posterior direction, the surface fully capable of cooperate with the lateral condylar structure of the femoral component to impart internal rotation on the tibia as the knee flexes from substantially zero degrees of flexion to substantially 130 degrees of flexion (as can be seen in the progression of figs. 16a-16f the knee can flex beyond 155 degrees and still maintain contact between 92 and 80 while being able to rotate >15 degrees, col 9-fig 12).

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With regard to claims 2-4, 21-23, 73-75, 91-93, the accommodation structure is a component that is mounted on a tibia and is part of an insert, which is adapted to fit between the femoral component and a tibial implant (figs. 10-11).

With regard to claims 5-7, 24-26 and 95-97, the posteriolateral surface (92) includes a portion that is convex (at 94), a portion that is substantially flat (towards 47") and that is substantially concave (where 92 is pointing in figure 11).

With regard to claims 8, 27, 76 and 92, comprising a tibial implant (40).

With regard to claims 10, 20, 29, 78, 88-90 and 100, the medial condylar structure of the femoral component is greater in size (as see in fig 3) than the lateral condylar structure of the femoral component, and the accommodation structure is thicker in at least some areas that cooperate with the lateral condylar structure of the femoral component than in corresponding areas that cooperate with the medial condylar structure of the femoral component (the corresponding areas of contact when rotation of >15 degrees between the accommodation structure and the condyles do have thicknesses as claimed, since the accommodating structure tapers towards the posterior).

With regard to claims 12, 31, 80, 98, 102 and 112, the accommodation structure comprises a raised portion (92) on a proximal surface and the femoral component includes a cam (81) having a surface for cooperating with an anterior surface of the raised portion in order to provide an anterior stabilizing force at some angles of flexion (as shown in figs. 16a-16f).

With regard to claims 13, 32, 103 and 113, The knee prosthesis of claim 1 wherein the accommodation structure comprises a raised portion (92) on a proximal surface and the femoral component includes a cam (81) which includes a surface for cooperating with a posterior surface

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of the raised surface on the accommodation structure in order to assist in imparting internal rotation to the tibia relative to the femur at angles of flexion between the tibia and the femur of 50 degrees or greater (as shown in figs. 16c-16f).

With regard to claims 14, 33, 72, 104 and 126, the cam has an asymmetrical shape such that the lateral side of the cam is larger (i.e. has a fillet as such as seen in fig. 1 and 4) than the medial side (i.e. the central portion of the cam towards the medial side from the lateral fillet).

With regard to claims 15, 34, 83, 105, 111 and 118, the knee prosthesis of claim 1 wherein the accommodation structure includes edges (where 92 is pointing in fig. 11) adjacent its proximal surface, which are rounded (concave, the transition between 92 and the side 88 inherently would be rounded to a small degree).

With regard to claims 17, 36, 85 and 107 lateral portions of the femoral component anterior surface extend further in an anterior direction than medial portions of the femoral component anterior surface (as shown in fig. 3), whereby the anterior surface of the femoral component is adapted to assist in precluding subluxation of the patella.

With regard to claims 18, 37, 86 and 108, the accommodation structure includes a proximal lateral surface with an arcuate swept surface (where 92 is pointing in fig. 11), the swept surface adapted to assist in guiding tracking of lateral structure of the femoral component on the proximal surface during at least some ranges of flexion between the tibia and the femur.

With regard to claims 119-122, the femoral portion 30 has interior surfaces (as can be seen in figures 2 and 3), which can be said or categorized as capturing (seizing, to acquires, taken) the femur when rotated onto the femur about its posterior portion.

With regard to claim 116, the anterior cam (at 38).

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With regard to claims 123 and 125, the internal anterior and posterior surfaces aren't parallel so they intersect as a small angle in the direction of the tibial.

Claims 1-123 and 125-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hood et al in view of Ries et al (US 5824105). Hood et al discloses a knee prosthesis as discussed above.

With regard to claims 10, 11, 19, 20, 30, 39, 55, 78, 79, 100 and 101 Hood et al does not disclose a line between the distal most surfaces of the medial condylar structure and the lateral condylar structure oriented at an angle of approximately 3 degrees from a line that is perpendicular to the mechanical axis of a leg. Ries et al teaches another knee prosthesis using the anatomically correct oriented at an angle of approximately 3 degrees from a line that is perpendicular to the mechanical axis of a leg for the purpose of functioning as the natural knee including a medial condylar larger than lateral condylar. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the knee of Hood et al using the anatomically correct oriented at an angle of approximately 3 degrees from a line that is perpendicular to the mechanical axis of a leg as taught by Ries et al in order to function similarly the a natural knee.

With regards to claims 19, 38, 70, 87, 109 and 114, Hood et al does not disclose the posterior surface of the medial condylar portion of the femoral component extends no farther than approximately 2 mm beyond the posterior surface of the accommodation structure at substantially full extension. The courts have held that changes in size/proportion and/or shape are prima fascia obvious modifications as a matter of mere design choice when the device would not

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perform differently from the prior art device and are therefore not patentably distinct. One of ordinary skill in the art could shrink the device for example to fit a child and the medial condylar would not extend beyond 2 mm at full extension. Likewise, the tibial/accommodation structure insert could be shaped to extend beyond the contacting surfaces without performing differently. Ries et al additionally teaches a medial condylar which does not extend as far to the posterior as the lateral condylar (fig. 19) as part of the teachings discussed above which would be "about" 2 mm beyond the tibia/accommodation structure insert as modified.

Allowable Subject Matter

Claims 124 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

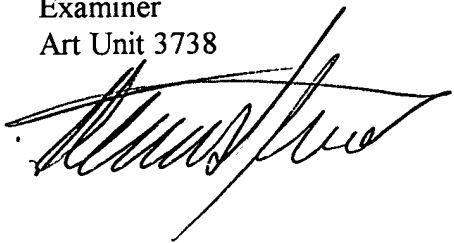
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 5:45am - 4:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas J Sweet
Examiner
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A handwritten signature in black ink, appearing to read 'Thomas J Sweet', with a large, sweeping flourish extending from the end of the signature.